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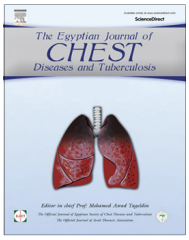

ORIGINAL ARTICLE

Tuberculosis situation in Ismailia governorate (2002–2012) before and after Direct Observed Therapy Short Course Strategy (DOTS)

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KEYWORDS

TB;
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Abstract *Background:* Tuberculosis (TB) is a major cause of illness and death worldwide, especially in Asia and Africa. In the early 1990s tuberculosis control in Egypt faced many problems. Major progress in global tuberculosis control followed the widespread implementation of the DOTS strategy.

Aim: The objective of this work was to study the tuberculosis situation in the Ismailia governorate from 2002 to 2012 before and after Direct Observed Therapy Short Course Strategy (DOTS).

Methods: This was a retrospective clinical cohort study carried out at the Ismailia governorate. The registered data about all TB cases over a period of 10 years (2002–2012) before and after the application of DOTS were collected from the chest hospital and TB registration units.

Percentages of cure treatment significantly increased after DOTS (55.3%) than before (40.5%) ($P < 0.01$). On the other hand, complete, failure, death, default and transfer out decreased after DOTS (32.5%, 1.3%, 6.3%, 2.5% and 2.0% respectively) than before it (38.7%, 3.1%, 6.9%, 7.2% and 4.0% respectively), the results were not significant ($P > 0.05$) for all of them. The mean values of incidence rates (new and relapse cases, all cases and new smear positive pulmonary TB cases) of TB highly significantly ($P < 0.01$) decreased after the application of DOTS for all of them except new smear positive pulmonary TB cases ($P > 0.05$). Also, the cure rate and treatment success rate significantly increased ($P < 0.05$), while retreatment TB cases rate, default rate, transfer out rate and retreatment failure rate did not significantly decreased ($P > 0.05$) for all of them except retreatment failure rate (chronic TB rate) ($P < 0.05$). Finally new pulmonary TB cases with no smear result significantly ($P < 0.05$) decreased after DOTS.

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Conclusion: The introduction of DOTS in the Ismailia governorate has led to a significant increase in the treatment success (88.07%) which is higher than the WHO target (85%), and a decrease in the default and failure rates.

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Introduction

Tuberculosis (TB) is an infectious disease that remains a major global health problem. It causes ill-health among millions of people each year and ranks as the second leading cause of death from an infectious disease worldwide, after the human immune-deficiency virus (HIV). In the latest estimates there were 8.6 million new TB cases in 2012 and 1.3 million TB deaths [15]. Most of the estimated numbers of TB cases in 2009 occurred in Asia (55%) and Africa (30%), with India and China combined accounted for 35% of all TB cases. The 22 high-burden countries (HBCs) that have received the particular attention at the global level since 2000 accounted for 80% of all estimated TB cases worldwide [15].

World Health Organization (WHO) has set the international target value for a treatment success outcome at 85% however the world wide success rates for tuberculosis range from 20% to 87% [7].

The DOTS guidelines recommend a short course regimen for newly diagnosed patients whose sputum shows smear positive results, which start with an intensive phase of four drugs (isoniazid, rifampicin, pyrazinamide and ethambutol) for two months followed by a continuation phase of rifampicin and isoniazid for four months, all given under direct observation of treatment [5].

Under DOTS, treatment may be given daily or three times weekly for both treatment phases. Additionally, in the intensive phase ethambutol may be replaced by the injectable streptomycin [13].

DOTS strategy has five key components as identified by WHO

Government commitment to sustained tuberculosis control activities includes case detection by sputum smears microscopy among symptomatic patients, standardized treatment regimen of 6–8 months for all confirmed sputum smear positive cases with DOTS for at least the initial 2 months, a regular UN interrupted supply of all essential anti-tuberculosis drugs, standardized recording and reporting system that allows assessment of treatment [12].

The primary key of DOTS strategy is the direct observation of tuberculosis treatment (DOT) by a supervisor, usually a health or community worker supervising TB patients to ensure they are taking their medications thus decreasing prolonged morbidity and drug resistance [2].

To date DOTS strategy remains the corner stone of global efforts for tuberculosis control and studies throughout the world indicate that by using DOTS strategy, the success rate of treatment is about 90–95% or even higher [7].

Microbial resistance to anti-tuberculosis drugs has existed since the dawn of the antibiotic era. Multidrug-resistant (MDR) tuberculosis defined by resistance to isoniazid and rifampicin, requires treatment for up to two years with expensive second line drugs and success rates rarely exceed 65–75%. Extensively drug-resistant(XDR) tuberculosis, refers to the disease caused by multidrug-resistant strains that are also resistant to treatment with any fluoroquinolone and any of the injectable drugs used in treatment with second-line anti-tuberculosis drugs (amikacin, capreomycin and kanamycin) [10].

Aim

The objective of this work was to study the tuberculosis situation in the Ismailia governorate from 2002 to 2012 before and after the application of Direct Observed Therapy Short Course Strategy (DOTS).

Methodology

This was a retrospective clinical cohort study carried out at the Ismailia governorate. The registered data about all TB cases over a period of 10 years (2002–2012) were collected from the TB registration units in the Ismailia governorate. This period includes 2 stages; four years (2002–2006) before the application of DOTS and six years (2007–2012) after it.

- **The Collected data included**:

(1) TB registration code and the year.
(2) Socio demographic data which included name, age, sex and residence.
(3) Forms of tuberculosis; Either: Pulmonary (either smear positive or smear negative) or extra pulmonary (and its site as LN, intestine, meninges, breast, renal).
(4) History of previous treatment if present (category of patients or type of the patient); either new, relapse, treatment after failure, treatment after default, transfer in or others.
(5) Schedule of treatment (recommended standardized treatment regimen) according to [8].
(6) The recorded follow up for smear-positive pulmonary tuberculosis included sputum smear microscopic examination for acid fast bacilli, at the end of 2nd month, at end of 5th month and at the end of treatment [8].
(7) Outcome: which included: Cure, treatment completed, treatment failure, died, default and transfer out.
(8) Culture result: The total number of cases examined yearly by culture and its result.

- **TB indicators** were designed by The World Health Organization [14] to determine national TB program (NTP) quality and effectiveness , these indicators are:

- Incidence rates (case notification rate): For new cases, new and relapse cases, all cases and new smear positive pulmonary cases.
- New pulmonary TB cases with no smear result.
- New adult smear positive cases.
- Re-treatment TB cases.
- New extra pulmonary TB cases.
- New TB cases with no smear conversion result.
- Sputum conversion rate at the end of the initial phase of treatment.
- Cure rate.
- Treatment completion rate.
- Death rate.
- Treatment failure rate.
- Default rate.
- Transfer out rate.
- Re-treatment failure rate (chronic TB rate).

– **Comparison of indicators before and after DOTS was carried out.**

Statistical analysis

The collected data were tabulated and analyzed using SPSS version 16 software, categorical data were presented as number and percentages while continuous variables were presented as mean and standard deviation. Chi square test, Fisher's exact test and Student "*t*" test were used. Microstat software was used to calculate "*Z*" test for 2 proportions of 2 independent groups. $P < 0.05$ was considered significant.

Results

The majority (38.0%) of the studied patients were between 15 and less than 30 years old. The highest percentage (68.0%) was males and 89.0% were from urban areas Table 1.

Table 1 Socio-demographic characters of the studied sample.

Variable		Total ($N = 1363$)	% 100.0
Locality	Eltal elkabeer	64	5.0
	Elkasasen	80	6.0
	Abo-suer	115	8.0
	Ismailia	855	63.0
	Faied	72	5.0
	Elkantara shark	67	5.0
	Elkantara gharb	110	8.0
The studied patients	Before DOTS (2002–2006)	763	56.0
	After DOTS (2007–2012)	600	44.0
Age	<15	117	9.0
	15–	513	38.0
	30–	372	27.0
	45–	247	18.0
	60+	114	8.0
Gender	Male	924	68.0
	Female	439	32.0
Residence	Urban	1216	89.0
	Rural	147	11.0

There was a statistically significant difference ($P < 0.01$) regarding the socio-demographic characters of patients before and after the application of the program, where, infection among younger ages (15– and 30–) decreased (11.1% and 38.0% before DOTS and 5.3% and 37.2% after DOTS). The percentage of infected males was lower after DOTS than before (64% and 72.5% respectively). Infection among rural residents also became lower after DOTS than before (9.7% and 11.7% respectively) Table 2.

Results showed also that percentage of pulmonary TB was lower after the application of DOTS (83.3%) than before (89.0%). Regarding the smear results at diagnosis, it was 52.7% before DOTS and became 66.3% after. The percentages of smear −ve cases at 2nd, 3rd, and 5th month and end of treatment were lower after DOTS than before (96.0%, 76.4%, 47.5% and 14.5% respectively after DOTS and (92.5%, 75.0%, 37.7% and 8.8% respectively before DOTS). All these differences were statistically significant ($P = 0.001$) for all. The table also shows that culture was done for only 1.2% of the studied patients Table 3.

This work found that the relapse did not significantly ($P > 0.05$) decrease after the application of DOTS. Regarding treatment outcome, it showed that the percentages of cure treatment highly significantly increase after DOTS (55.3%) than before (40.5%) ($P > 0.01$). On the other hand, complete, failure, death, default and transfer out did not significantly decrease ($P > 0.05$) after DOTS (32.5%, 1.3%, 6.3%, 2.5% and 2.0% respectively) than before DOTS (38.7%, 3.1%, 6.9%, 7.2% and 4.0% respectively) in Table 4.

The mean values of incidence rates (new and relapse cases, all cases) of TB highly significantly ($P < 0.01$) decreased after the application of DOTS except for the incidence rate of new smear positive pulmonary TB cases ($P > 0.05$). Also, the cure rate and treatment success rate did not significantly increase ($P > 0.05$), and so default rate, transfer out rate and treatment failure rate did not significantly decrease ($P > 0.05$) except for the retreatment failure (chronic TB cases rate) ($P < 0.05$) Finally new pulmonary TB cases with no smear result significantly ($P < 0.05$) decreased after DOTS Table 5.

Discussion

This study investigated the situation of tuberculosis in the Ismailia governorate from January 2002 to December 2012, before and after the application of Direct Observed Therapy Short Course Strategy (DOTS). The total number of the recorded tuberculous cases was 1363; 763 cases before DOTS and 600 cases after.

This work revealed that the highest prevalence (by age) of TB was among individuals aged 15– < 30 years (38.0%), and the lowest prevalence was among those of age extremes. This could be explained by the increased prevalence of smoking behavior among this active age group in our society. Moreover, poverty, malnutrition, physical, mental, and occupational stress and more exposure to infection are other contributing factors. El-Zeheiry [3], conducted a retrospective study in the Dakahlia governorate, Egypt to review the TB situation, she found that tuberculosis was common among the middle aged group from 15– < 30 years (32.3%). Similar results were drawn in the El-Menoufia governorate (1992–2008) Abdelghany [1], and in El-Gharbia governorate

Table 2 Socio-demographic characters of the studied patients before and after the application of DOTS.

Variable		Before DOTS (N = 763)		After DOTS (N = 600)		Total (N = 1363)		χ^2	P
		No	%	No	%	No	%		
Age	< 15	85	11.1	32	5.3	117	8.6	19.6	0.001**
	15–	290	38.0	223	37.2	513	37.6		
	30–	204	26.7	168	28.0	372	27.3		
	45–	119	15.6	128	21.3	247	18.1		
	60+	65	8.5	49	8.2	114	8.4		
Gender	Male	489	64.0	435	72.5	924	68.0	10.88	0.001**
	Female	274	36.0	165	27.5	439	32.0		
Residence	Urban	674	88.3	542	90.3	1216	89.0	1.39	0.24
	Rural	89	11.7	58	9.7	147	11.0		

Table 3 Site, smear and culture results among the studied patients before and after the application of DOTS.

Variable		Before DOTS (N = 763)		After DOTS (N = 600)		Total (N = 1363)		χ^2	P
		No	%	No	%	No	%		
Site of TB	Pulmonary	679	89.0	500	83.3	1179	86.5	9.21	0.002**
	Extra pulmonary	84	11.0	100	16.7	184	13.5		
Sputum smear at diagnosis	+ve	402	52.7	398	66.3	800	58.7	25.8	0.001**
	−ve	361	47.3	202	33.7	563	41.3		
		(N = 402)		(N = 398)		(N = 800)			
Sputum smear at 2nd m†	+ve	28	7.0	11	2.8	39	4.9	8.81	0.012*
	−ve	372	92.5	382	96.0	754	94.2		
	Not done	2	0.5	5	1.2	7	0.9		
Sputum smear at 3rd m†	+ve	20	5.0	9	2.3	29	3.6	4.31	0.116
	−ve	302	75.0	304	76.4	606	75.8		
	Not done	80	20.0	85	21.3	165	20.6		
		(N = 763)		(N = 600)		(N = 1363)			
Sputum smear at 5th m*	+ve	15	2.0	8	1.3	23	1.7	13.36	0.001**
	−ve	288	37.7	285	47.5	573	42.0		
	Dropouts	460	60.3	307	51.2	767	56.3		
Sputum smear at end treatment†	+ve	9	1.2	1	0.2	10	0.7	15.27	0.001**
	−ve	67	8.8	87	14.5	154	11.3		
	Dropouts	687	90.0	512	85.3	1199	88.0		
Culture results	+ve	1	0.1	6	1.0	7	0.5	7.77	0.02*
	-ve	3	0.4	7	1.2	10	0.7		
	Not done	759	99.5	587	97.8	1346	98.8		

† Among the smear positive cases at diagnosis.

(1994–2010) where the highest prevalence of TB occurred among the age group 15– < 30 years (34.72%), (33.7%), respectively and the lowest prevalence occurred in extremes of age [4]. In the present study, tuberculosis was common among men (67.8%) than women (32.2%). This could be explained by the fact that males are more active and are exposed to stress more than females. Also, many females may not seek medical advice due to factors related to illiteracy, cultural and traditional attitudes which may neglect the females' health status. Higher tuberculosis notification rates among men may partly indicate differences in exposure due to more frequent social contacts, risk of infection and progression from infection to disease caused by gender differences in association with other risk factors for tuberculosis such as alcohol abuse and smoking which are associated with pulmonary tuberculosis. Similar results were obtained by Floyd et al. [6], they found that male cases were 80.2% and female cases were 19.8%.

Urban cases (89.0%) were higher than rural cases (11%). Increased tuberculous cases in urban areas could be explained by what is reported by, [9] who conducted a study about costs and outcomes of tuberculosis in the Russian Federation, they found that urban cases (80.8%) were significantly higher than rural cases (19.2%). They explained this result by demographic changes like increasing life expectancy, population growth, and deterioration of living conditions in urban areas like overcrowding and epidemiological factors like HIV epidemics. Also it may be due to the shift of people from rural to urban areas.

Table 4 Type of patient and treatment outcome among the studied sample before and after the application of DOTS.

Variable		Before DOTS (763)		After DOTS (600)		Total (1363)		Z	P
		No	%	No	%	No	%		
Type of patients	New	683	89.5	547	91.2	1230	90.2	4.21	0.001 HS (< 0.01)
	Relapse	40	5.2	36	6.0	76	5.6	0.459	0.323 NS
	Failure	10	1.3	7	1.2	17	1.2	0.0	0.5 NS
	Defaulter	11	1.4	7	1.6	18	1.3	0.218	0.414 NS (> 0.05)
	Transfer	10	1.3	0	0.0	10	0.7	–	–
	Others*	9	1.2	3	0.5	12	0.9	0.504	0.307 NS
Treatment outcome	Cure§	309	40.5	332	55.3	641	47.0	0.909	0.001 HS
	Complete	295	38.7	195	32.5	490	36.0	7.75	0.05 NS
	Fail	23	3.1	8	1.3	31	2.3	0.541	0.29 NS
	Death	53	6.9	38	6.3	91	6.7	1.59	0.055 NS
	Default	55	7.2	15	2.5	70	5.1	0.0	0.5 NS
	Transfer out	28	3.7	12	2.0	40	2.9	0.96	0.17 NS

*Others groups include: chronic cases, patients who are sputum positive at the end of a re-treatment regimen.
§ For smear positive cases.

Table 5 Tuberculosis indices before and after the application of DOTS.

	Indices	Before DOTS		After DOTS		T test	P^*	Statistical significance
	Mean Indicator	Mean before DOTS	SD	Mean after DOTS	SD			
1	Incidence rate: new cases	12.22	1.72	8.01	1.72	4.04	0.003	HS (< 0.01)
2	Incidence rate: new and relapse cases	12.98	1.87	8.55	2.01	3.75	0.005	HS
3	Incidence rate: all cases	13.66	1.85	8.95	2.1	3.9	0.004	HS
4	Incidence rate new smear positive pulmonary TB cases	5.96	1.11	5.07	0.96	1.42	0.189	NS
5	New pulmonary TB cases with no smear result	30.82	5.48	19.1	7.31	2.95	0.016	S
6	New adult smear positive cases	54.75	8.15	72.76	13.83	2.55	0.031	S
7	Retreatment TB cases	10.5	2.65	10.24	3.61	0.132	0.898	NS (> 0.05)
8	New extrapulmonary TB cases	21.36	1.41	19.03	4.24	1.16	0.274	NS
9	New TB cases with no smear conversion result	5.74	2.68	3.35	1.89	1.74	0.116	NS
10	Sputum conversion rate at the end of the initial phase of treatment	69.73	16.53	80.23	4.08	1.52	0.164	NS
11	Cure rate	80.39	8.24	87.23	2.74	1.93	0.086	NS
12	Treatment completion rate	6.48	5.44	0.84	0.93	2.52	0.033	S
13	Treatment success rate	86.87	3.43	88.07	3.0	0.618	0.552	NS
14	Death rate	4.78	3.09	4.29	2.16	0.315	0.76	NS
15	Treatment failure rate	2.81	3.82	2.57	1.11	*Z = 0.55	0.582	NS
16	Default rate	4.78	1.19	3.55	1.62	1.41	0.193	NS
17	Transfer out rate	0.75	1.04	1.52	1.74	*Z = 0.896	0.37	NS
18	Retreatment failure rate (chronic TB rate)	10.25	7.48	1.19	2.91	*Z = 2.29	0.022	S

In contrast, Khalifa [4] carried out a retrospective study in Gharbia governorate (1994–2010), that stated that rural cases (61.7%) were significantly higher in comparison with urban cases (38.3%). Abdelghany [1], conducted a similar study in the Menoufia governorate (1992–2008), he concluded that rural cases (80.05%) were also significantly higher than urban cases (19.95%) during all years of the study. Similar findings have been reported by El-Zeheiry [3], in Dakahlia governorate (2006–2011). Increased tuberculous cases in rural areas could be explained by poverty and bad social conditions and milk sanitation, also agricultural workers may acquire occupational infection by bovine bacilli from the infected animals. Moreover, it may be due to better notification of rural cases due to improved access to health care through decentralization of the services and improved patient follow up with the introduction of DOTS [11].

The current study revealed that infection among younger ages (15− and 30−) mildly decreased (11.1% and 38.0% before DOTS and 5.3% and 37.2% after DOTS respectively). The percentage of infected males was not significantly decreased after DOTS than before (72.5% and 64% respectively) ($P > 0.05$). Infection among rural residents also became lower after DOTS than before (9.7 and 11.7%, respectively) (Table 2). These findings reflect the changes that occurred in the socio demographic characters among patients, where the proportion of the younger age group decreased, males became less infected and improvement in the health services in rural areas led to a reduction in the percentage of the affected rural individuals.

In the present study there was an increase in extra pulmonary cases (from 11.0% to 16.7%) with a decrease in pulmonary cases (from 89% to 83.3%) before and after DOTS respectively (Table 3). This indicates more control of the pulmonary cases. Moreover, the increase in the extra pulmonary cases may be a false increase explained by more availability of diagnostic facilities such as specified X-rays or biopsy procedures which are necessary to detect extra pulmonary tuberculosis. Increased life expectancy which may be associated with reactivation of a latent tuberculous lesion from pulmonary sites and more physical contact with infected animals may also be implicated.

This work reported that the sputum conversion rate increased after DOTS at the end of the second month, third month, fifth month and at the end of the treatment (Table 3). This reflects more treatment success that is due to new regimens of treatment with Rifampicin for six months, direct observation of cases under treatment and good follow up of patients. These results agree with [1,3,4]. The increase in the conversion rate in this study and all the mentioned studies means high efficacy of applying DOTS in chest hospitals and dispensaries. There is also an increase in the number of cases examined for their sputum.

As diagnosis of tuberculous cases depends mainly on direct smear examination of sputum by Z.N. staining, the role of culture in diagnosis of cases was limited. As shown in this study the number of cases examined by culture technique all over the years was only 17 (1.2%) (Table 3). Similar findings have been obtained by [1,4]. Lack of culture and sensitivity test use at the studied chest units may be due to that the indications of culture in DOTS include only; failure of re-treatment cases, seriously ill cases, extra pulmonary cases, smear negative cases, childhood TB and HIV-TB, for multidrug resistant TB (MDR TB), not for new smear positive cases [13].

The comparison between the type of patient based on previous history of treatment before and after DOTS showed a statistically significant increase in the new cases (Table 4). The increased percentage of new cases after DOTS indicates the efficacy of diagnosis and early detection of tuberculosis. Also, it was found that Failure cases decreased after DOTS, this result denotes the efficacy of applying DOTS, efficacy of treatment and attendance of patients to take their treatment regularly.

This study revealed that the most common type of patients was new cases, which coincide with [1,3,4], who found that new cases represented the highest percentage of cases attended for treatment.

This study showed a significant improvement in all parameters of treatment outcome (expect for treatment failure) after DOTS, which means a good impact of applying DOTS in the chest hospitals and dispensaries. There was a marked decrease in the percentage of defaulters which constitutes a great problem during tuberculosis treatment. Treatment failure may be due to poor compliance of the patient or to practitioner error, e.g. in cases where inadequate regimens and or shortened periods of treatment are prescribed. Drug resistance may also be implicated. Unsuccessful treatment may result from irregularity in taking treatment and loss of follow up, which may be due to patients being transferred to another unit. Moreover, many patients stop treatment as soon as they feel better.

The current research declared that the mean values of incidence rates (new and relapse cases, all cases and new smear positive pulmonary TB cases) of TB were significantly ($P < 0.05$) decreased after the application of DOTS. Also, the cure rate and treatment success rate did not significantly increase ($P > 0.05$), while retreatment TB cases rate, default rate, transfer out rate did not significantly decrease ($P > 0.05$) but the retreatment failure TB cases significantly decreased ($P < 0.05$), and finally new pulmonary TB cases with no smear result significantly ($P < 0.05$) decreased after DOTS (Table 5). Increased coverage by short course chemotherapy, improved access to care through decentralization of the service and improved patient follow-up with the introduction of DOTS was observed that most likely played a significant role in improving the treatment outcomes.

Limitation of the study

Although this success of DOTS was seen there are points of weakness in the Ismailia governorate Chest hospital; the high percentage of sputum negative cases (17.2%) may be false due to the decrease in the facilities of diagnosis in the governorate hospitals. 2.9% of tuberculous cases were transferred out, we have no idea about the outcome of these groups. Fewer culture results were registered about TB cases.

Conclusion

The introduction of DOTS in the Ismailia governorate has led to a significant increase in treatment success (88.07%) which is higher than the WHO target (85%), and a decrease in default and failure rates.

Recommendations

Poor patient knowledge regarding tuberculosis may be a significant predictor of treatment failure, so strengthening health education in the DOTS strategy is therefore recommended. Patients with tuberculosis need more and more social and psychological support to decrease defaulters and treatment failure. A special registration system for the transfer out cases using a computer system with their national numbers is needed to trace the outcome of these cases.

Conflict of interest

There is no conflict of interest.

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